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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,492	11/20/2003	Christopher C. Toly	SIMU0004	8227

25268 7590 10/09/2007

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EXAMINER	
MUSSELMAN, TIMOTHY A	
ART UNIT	**PAPER NUMBER**
3714	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,492	TOLY, CHRISTOPHER C.	
	Examiner	Art Unit	
	Timothy Musselman	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-9,15,16,20-35,37-61 and 74-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-9,15,16,20-35,37-52,55-61 and 74-87* is/are rejected.

7)☒ Claim(s) *53 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

In response to the communication filed 7/19/2007, claims 1-3, 7-9, 15-16, 20-35, 37-61, and 74-87 are pending. Claims 4-6, 11-14, 17-19, and 36 have been withdrawn from consideration as a non-elected species subject to rejoinder upon allowance of a generic claim. Claims 42, 46, and 62-73 have been cancelled as being directed to a non-elected invention. Claims 13 and 47 have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 1-3, 7, 10-37, 43-50, 55-74, 76, 78-79, and 82-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls (US 2003/0068606) in view of Eggert et al. (US 5,853,292).

Regarding claim 2-3, 7, 16, 24, 45, 48, 55, 57-61, 74, 79, and 85, Nicholls discloses a simulated physiological tissue structure comprising a conductive elastomer evaluation circuit comprising multiple conductive layers not electrically connected to each other and configured to provide a signal for feedback regarding the performance of a simulated medical procedure. See paragraphs 13 and 14. Nicholls does not disclose wherein the evaluation signal does NOT require current from an instrument placed in contact with the evaluation circuit (i.e. Nicholls DOES require the current from the instrument), and also wherein

the feedback signal is due to a completion of a circuit between different conductive layers. However, Eggert teaches of a medical simulation device that comprises multiple woven conductive layers, wherein an inserted medical instrument completes a circuit between the layers to indicate proper performance of a medical procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this technique as an option into the conductive layers of Nicholls, in order to provide versatility with regard to sensory and data acquisition options and expand the training uses for the device.

Regarding claims 1 and 15, Nicholls fails to teach wherein the system provides a signal when the circuit is opened. However, Eggert teaches of this concept in col. 5: 38-46. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize evaluation circuits that use various sensor types and concepts as taught by Eggert with the conductive elastomer pathways in the system of Nicholls, in order to provide additional sensor types and training uses for the system.

Regarding claim 20, Nicholls further discloses wherein the circuit comprises multiple evaluation circuits comprising conductive elastomer, and wherein each circuit provides a signal when the particular portion of the structure is manipulated. See paragraph 0014.

Regarding claims 21-22, 49-50, and 76, Nicholls further discloses wherein the simulator comprises an indicator (light source) coupled to the evaluation circuit, such that in response to the signal the indicator provides an indication relating to the performance of the simulated procedure. See paragraph 29.

Regarding claim 23, Nicholls further discloses wherein the indicator comprises a meter. See paragraph 27.

Regarding claim 25, Nicholls further discloses wherein the structure comprises at least one simulated membranous layer comprising an elastomeric layer, and at least one simulated sub-membranous layer comprising an elastomeric layer. See paragraphs 0013 and 0014.

Regarding claims 26-28, 56, and 86, Nicholls further discloses wherein the evaluation circuit is implemented as a 3D grid encompassing a majority of the structure.

Regarding claims 29-30, Nicholls discloses fluid channels (paragraph 0013), but fails to teach wherein the sensor circuit is embedded in the walls to detect damage. However, Eggert teaches of the concept of sensors in the walls of simulated arteries in col. in col. 5: 18-36. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the circulatory system wall detection of Eggert with the elastomer evaluation circuits of Nicholls, in order to increase the training versatility of the training system of Nicholls.

Regarding claim 31, Nichols further discloses wherein the evaluation circuit is coupled to a processor configured to manipulate the signal. See paragraph 29.

Regarding claims 32-33, 78, and 82-84, Nicholls discloses a physiological control element configured to produce a simulated physiological response in the simulated physiological structure including a pump. See paragraph 25. Nicholls fails to teach of the physiological control element being coupled to the evaluation circuit so that the processor uses the evaluation circuit to control the physiological control element, and wherein the control element includes a servo. However, Eggert teaches of these features in col. 4: 45-60. It would have been obvious to one of ordinary skill in the art at the time of the invention to include these mechanical feedback systems in the invention of Nicholls in order to increase the versatility of the training device and provide additional realism.

Regarding claim 34, Nicholls further discloses wherein the simulated physiological structure where the simulated procedure will be performed, so that by monitoring the plurality of branches, the processor determines a three-dimensional location of an instrument during the simulated procedure. See paragraph 14.

Regarding claims 35 and 43-44, Nichols further discloses wherein the simulated structure is a surgical trainer that is an organ, and the trainer comprises an outer cover with an opening to access the simulated tissue structure, and wherein the simulated tissue structure comprises multiple layers including a conductive layer. See paragraph 10.

Regarding claims 37 and 87, Nicholls further discloses a neural network that substantially corresponds to a neural network in a physiological structure upon which the simulated physiological structure is modeled. See paragraph 28.

Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606) in view of Eggert et al. (US 5,853,292) , and in further view of Strover et al. (US 5,967,790).

Regarding claims 38-41, Nicholls discloses wherein the evaluation circuit is disposed proximate to a location on the simulated physiological structure at which a medical device will be employed in the simulated medical procedure, to evaluate whether a person performed the procedure properly (claims 39 and 41). See paragraph 14. Nicholls/Eggert fail to teach wherein the simulated physiological structure comprises a simulated joint or bone. However, Strover discloses a surgical training device that includes a knee joint and accompanying bone structure. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the joint and bone aspects of Strover into the simulation device of Nicholls/Eggert, in order provide additional and diverse training opportunities for the user.

Claims 8-9 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls (US 2003/0068606) in view of Eggert et al. (US 5,853,292) and in further view of D'Antonio et al. (US 5,589,639).

Regarding claims 8-9 and 51-52, Nicholls/Eggert disclose an evaluation circuit to determine the position and correctness of the simulated medical device relative to the simulated structure as described above, but fail to explicitly teach wherein the evaluation circuit comprises a capacitance sensitive switch, (claim 8), a resistance sensitive switch (claim 9), and wherein the simulated medical device includes an inductor wherein the evaluation circuit is configured to receive a current induced by the inductor when the simulated medical device is correctly utilized to perform the simulated medical procedure, (claim 51), and wherein the evaluation circuit comprises a capacitance based sensor (claim 52). However, D'Antonio teaches of a device for use in medical procedures that is directed towards solving the problem of sensing parameter changes in an environment and producing a corresponding signal. See col. 5: 21-27, wherein D'Antonio teaches of a Schmitt trigger switching device that is dependant upon a resistive, capacitive, or inductive signal from the respective sensors. D'Antonio further discloses an inductor to induce a signal to the sensing circuit. See col. 4: 45-50. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Nicholls/Eggert to include the sensor and switch types of D'Antonio, so as to provide an effective manner in which to sense and transform the physical parameters of the simulation into electrical signals for processing and display.

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls (US 2003/0068606) in view of Eggert et al. (US 5,853,292), and in further view of Pugh (US 6,857,878).

Regarding claim 75, NichollsEggert failsto teach wherein the indication produced by the evaluation circuit is provided to another party, so that the person is unaware of the indication during the execution of the simulated medical procedure. However, Pugh teaches of this feature in col. 8: 25-35. Therefore, it

would have been obvious to one with ordinary skill in the art at the time of the invention to incorporate this feature of Pugh into the system of Nicholls/Eggert, in order to allow for complete procedures to be carried out before feedback is given so that a students skill can be accurately tested.

Claims 77 and 80-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls (US 2003/0068606) in view of Eggert et al. (US 5,853,292), and in further view of Beach et al. (US 6,857,878).

Regarding claims 77 and 80-81, Nichols/Eggert disclose a physiological training and evaluation simulator comprising a simulated physiological structure including a conductive elastomer-based evaluation circuit configured to provide data relating to a simulated procedure being performed on the simulated physiological structure and a controller coupled to the conductive elastomer-based evaluation circuit, the controller being configured to implement a plurality of functions. See the rejections of claims 2 and 31 above. Nicholls/Eggert fail to teach of processing the data obtained from the conductive elastomer-based evaluation circuit to determine a score rating a quality of the simulated procedure and storing said scores for later comparison to determine a rate of learning. However, Beach teaches of a surgical simulation device that includes these features. See col. 11: 66-67, and col. 12: 43-48. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the scoring aspects of Beach into the system of Nicholls/Eggert, so as to allow users of the simulation to monitor their performance and improvements therein.

Allowable Subject Matter

Claim 53 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims are allowable over the prior art because the prior art does not teach wherein the

system is configured to indicate a successful procedure depending in the removal of a nonconductive segment of an evaluation system followed by the joining of two conductive segments.

Response to Arguments

Applicants arguments dated 7/19/2007 have been fully considered, but are moot in view of the new grounds of rejection. However, examiner notes that many of the arguments and examples provided in applicants submitted arguments do not pertain to claimed matter. While the examples provided clearly distinguish over the prior art of record, the claims as presented do not necessarily do so. For example, applicant *claims* wherein the evaluation circuit comprises a conductive elastomer portion. Examiner notes that this could simply be a matter of conductive elastomer segments leading to standard sensors that are known in the art, and the combination of the elastomer conductors of the Nicholls reference with systems that use these standard sensors would therefore be obvious. *Without commenting as to prior art potentially yet to be discovered*, the prior art of record thus far (with the exception of the Nicholls reference) does not disclose the use of elastomer portions of circuits for many of the sensory techniques of the evaluation circuit as applicant has described in the specification, particularly with regard to aspects wherein the simulated tissue structure itself is the sensory system. Examiner believes that careful rewording to this effect could potentially overcome many or all of the above rejections with regard to the prior art currently of record. This action is made non-final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy Musselman whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Robert Pezzuto
Supervisory Primary Examiner
Art Unit 3714